National Registry of Certified Chemists

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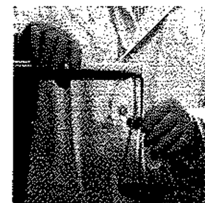
American Chemical Society
American Institute of Chemists
American Board of Clinical Chemistry
American Industrial Hygiene Association
National Academy of Clinical Biochemistry
American Association for Clinical Chemistry



Nevada State Board of Health Hearing
Support for proposed change #6 to NAC 652

The Nevada State Board of Health has proposed expanding the certifications that an applicant who holds a doctorate can use to qualify to be a licensed or registered laboratory director.

The National Registry of Certified Chemists (NRCC) began certifying chemists in clinical chemistry in 1967 and in toxicological chemistry in 1982. NRCC is an approved Certification Board by CLIA for Laboratory Directors of High and Medium Complexity Testing who hold a doctorate degree. NRCC manages certification programs for chemists in clinical, toxicological, and environmental analytical disciplines as well as a program for laboratory safety personnel.

Standards for certification of Clinical Chemists are vigorous; these include documenting education (a minimum of 24 semester hours of chemistry plus an additional 8 hours in other natural science disciplines), a minimum of three years of experience working in a CLIA approved clinical laboratory handling human specimens, a personal statement, three professional references, and an examination. NRCC also requires documentation of continuing education on an ongoing basis. The Clinical Chemistry examination is completely up to date, having been revised over the past year and implemented beginning February 15, 2017. The NRCC Board of Directors includes several clinical lab professionals who have been active with other professional Boards which are currently accepted by Nevada Board of Health for laboratory director licensing.

NRCC certification is accepted in nearly every state that requires Board certification for licensing purposes (all except New York). California, Louisiana, Tennessee & Florida are among the states with vigorous licensing requirements; all those states accept NRCC certifications for licensing. In addition to Laboratory Director positions, NRCC certifies laboratory personnel as clinical chemistry technologists and toxicological technologists. These certification programs are currently accepted by the Nevada Board of Health for licensing of laboratory technologists in those disciplines.

The NRCC Board of Directors is comprised of professionals in their fields who have been nominated by one of our association sponsors. These include the American Board of Clinical Chemistry (ABCC), American Association of Clinical Chemistry (AACC), American Chemical Society (ACS), the American Institute of Chemistry (AIC), and the American Industrial Hygiene Association (AIHA).

NRCC currently has approximately twenty certified chemists who are residents of Nevada.

2017 NRCC Board of Directors: David Blye, President; Dr. Laurence Doemeny; Marie Bevier; Dr. Mark Marzinke; Dr. Alina Sofronescu; Robert West, Dr. Steven C. Kazmierczak; Dr. Christopher R. McCudden; Stefan Wawzyniecki; Richard O'Meara; Russ Phifer, Executive Director.

To: Nevada State Board of Health

From: Nevada Assisted Living Association

Re: Intent to Adopt Regulations (LCB File No. R149-15)
Clarification on Requirement and Effects on Adult Group Care both licensed and unlicensed or certified

With the renewals for the 2017 calendar year came the option within our industry to become an exempt laboratory that only performs glucose testing. NALA wants to clarify two very different items which are before us in current legislation and regulatory settings.

First, is giving assistance with an FDA approved, personal, non-shared, glucometer as would occur in a home setting where a person lives permitted? The doctors of the post-acute care subcommittee and CLIA agree that it is safe and should be allowed. Our facilities are licensed as nonmedical facilities.

CMS and CLIA both agree that not sharing a meter is safe and cost effective. That combined with the safe, efficient, consistent, home / community based system of care that already includes accurate documentation, recording and reporting to the Primary Care Physician offered under monitored RFFG settings is a safe alternative to the proposed regulation. RFFG have an established monitored system to build on for documenting, recording, and adding glucose testing with an individual's own FDA approved machine to the existing RFFG medication management program. That would allow those who need help to get it safely and add no cost to the health care budget.

CLIA and CDC already acknowledge in their interpretive guidelines and other lecture material that using your own individual FDA approved meter is safe.

See CLIA Interpretive Guidelines 493 (b) which confirm that if a person is using their own individual FDA approved meter that "just getting assistance" does not require a CLIA Waiver. They distinguish the "Laboratory" which is a setting where one is expected to share the testing device.

pg 49 / 414 pgs Clia interpretive guidelines.

Interpretive Guidelines §493.3(b)

The purpose for which the test is conducted, not the test itself, determines whether a facility conducting testing is subject to the CLIA requirements. Testing that is used to gather evidence for legal purposes, and is not performed for purposes of clinical treatment, medical diagnosis, health assessment or disease prevention is not subject to CLIA.

Industrial laboratories that monitor employee health, insurance company laboratories tha[t] assess an individual's health for insurance purposes, health maintenance organizations, and other facilities such as pharmacies and health fairs that perform screening test procedures are subject to *the* CLIA requirements.

> When you expect to Share a meter like in street fair, lab, or any setting where the resident is not expected to bring their individual meter you need a Clia Waiver!

Individuals who self-administer a test in their own home with a device that has been cleared specifically for home use by the FDA are not regulated under CLIA. *An employee of a* home health agency (HHA) or hospice that *provides assistance to an individual as that individual uses such a device is not,* by virtue of that *assistance, subject to CLIA.* However, an HHA or hospice that performs laboratory testing on individuals *such that they meet* the definition *of* "laboratory" in §493.2 is subject to CLIA requirements. Getting assistance is not the issue, using a shared meter is

Another example that shows CDC and CLIA distinction of using an individual, non- shared meter and a laboratory sharing the meter is CLIA and point of care testing 12/8/2011 Karen Dyer who describes that a finger stick done with an individual FDA approved meter pose's no reasonable risk of harm to the patient if the test is performed incorrectly. That is not the case when using a shared testing device which is why CLIA exists to protect those who get tested in a shared testing setting.

Waived Tests....

- Simple laboratory examinations and procedures
- Cleared by FDA for home use; Individual, non shared, FDA approved, home glucometer
- Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

CLIA CMS

Consequently, facilities that utilize non-shared meters should not be required to obtain a CLIA exempt lab registration or license. They clearly distinguish that sharing a meter in a facility or lab is not safe and therefore needs the CLIA waiver.

The Second issue is when a facility opts to share a testing meter and thus needs a CLIA exempt lab registration or license, the allowance for a nurse to be the lab director when by regulation nurses employed by Residential Facilities For Groups under 449 cannot practice as a nurse in the area of diabetic care. This raises a safety concern because of the disconnect between the nurse and the oversight of the lab setting not meeting recognized laboratory safety guidelines nor bringing proficiency testing standards in line with federal regulation requirements. Infection Preventionist Nurses exist in other settings and we find no problem with a Nurse Practitioner as Lab Director as well.

NALA has made objections in previous workshops and small business impact statements on both of these issues.

The issue is not one test or one glucose test but that they are sharing the testing device and the expectation of documenting, recording and reporting the information which puts people at risk. The risks are not only from infection. The risks include lack of standardization of the test results, poor recording and reporting to the provider who will ultimately use the results. These are clearly issues to CLIA in their study all of which are not addressed in the proposed regulation allowing a nurse to be a medical lab director of a one glucose CLIA waived lab within our setting.

As a result of the aforementioned it is clear **that the anticipated adverse effects could be more than none** as stated in the Public Hearing notes. The interaction of the lab director in the laboratory's operations is a clear expectation of the exempt lab.

Thank you in advance of your consideration of these 652 or non 652 areas in the adult group care nonmedical settings.

Affidavit of Steven R. Feller, 2-28-17

My name is Steven R. Feller

Thank you for the opportunity to offer some perspective on the current situation regarding care of diabetics in assisted living homes, in Nevada. I believe this is a story of unintended consequences of a well-meaning regulation, perhaps outdated now, originally promulgated to help and protect some of our most vulnerable citizens who are elderly and suffering diabetes. One of those citizens is my brother-in-law, Meliton Ramirez.

I won't recount all the details of Mel's life except that he spent 25 years working for the Railroad, and 10 plus years at MeadowWood Mall. But age, diabetes, and other diseases caught up to him one day in 2013, and he collapsed near the door to his private apartment. After approximately a year in and out of the VA Hospital, his health stabilized enough to place him in Assisted Living. He lost so much weight that diabetes testing was unnecessary, as the doctors watched his 1AC results, and he took Metformin, occasionally.

Naturally, my wife and I were glad to find an assisted living facility to care for Mel because we live 225 miles away, and could not cope with his daily needs, including medication management and close personal safety monitoring. Mel spent 3 ½ very good years at Park Place Assisted Living before his next medical problem landed him in the hospital again. He recovered and was sent to a skilled nursing facility for rehabilitation, and his room at Park Place was held for him.

What happened next surprised us. The doctors at the skilled nursing home saw "diabetes" in his medical record from the VA and ordered daily testing for blood sugar, even though he had not needed daily testing for over three years. That had the unintended consequence of blocking his return to Park Place Assisted Living because regulations would not allow anyone at the assisted living facility to do the actual testing. What's difficult to understand is why the people who work at Park Place can't help him with diabetes testing when necessary. It seems unusual that the regulations contemplate that the patient or members of his family could take care of the testing, but trained personnel accustomed to dealing with all manner of medical situations at assisted living were prohibited.

We thought that Mel entered Park Place Assisted Living knowing his care needs would increase and fully expecting to be able to get what he needed in reasonable accommodations and assistance when needed if or when he needed help.

We were taken by surprise when Mel was suddenly and unexpectedly forced to stay in a nursing home and leave his home. He was forced to rely on Medicaid to help with the expenses, because his Railroad Pension and VA Aid & Attendance did not cover even a third of the cost of skilled nursing.For the hundreds of people like him that have diabetes and have any minor physical or cognitive issue and need help with a finger stick the only state allowed place is a nursing home. The state should allow diabetics to get routine assistance with a glucometer since the CDC, CMS and Clia clearly show it is a very safe process to use an FDA approved meter.

We don't understand the interpretation when the Federal Olmstead Act was pushing to help allow the disabled like Mel to have reasonable, safe, accommodations to help prevent institutionalization. The result was at a time when he was needing more assistance to remain at the assisted living stage, he was forced by the state's regulations to remain in a nursing home.

Please support a more reasonable interpretation of existing Federal law and help pass laws that give regulators clearer guidelines on allowing Nevadans in all home and community based settings to get help when needed with their own FDA approved individual glucometer. Indeed, many Federal laws protects that choice for the many disabled including diabetics in this case who choose to get a little help with their own individual glucometer in their own community based home setting.

Sincerely,

Steven R. Feller
Mel's Brother-in-Law
Berkeley, California

ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

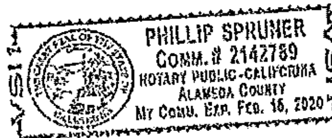
State of California
County of Alameda)

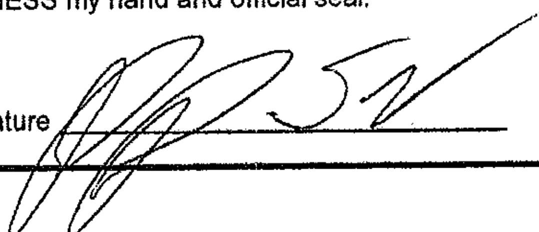
On 3/2/17 before me, Phil Spruner, Notary Public
(insert name and title of the officer)

personally appeared Steven Robert Feller,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.



Signature  (Seal)